K113374

510(k) SUMMARY

JUL 13 2012

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	July 11, 2012	
Device:	Trade/Device Name:	ACE Albumin Reagent
	Regulation Number:	21 C.F.R. § 862.1035
	Regulation Name:	Albumin Test System
	Regulatory Class:	Class 2
	Product Code:	CIX
	Common/Classification Name:	Bromcresol Green Dye-Binding, Albumin
	Trade/Device Name:	ACE Total Protein Reagent
	Regulation Number:	21 C.F.R. § 862.1635
	Regulation Name:	Total Protein Test System
	Regulatory Class:	Class 2, Exempt, meets limits of exemptions per 21 CFR § 862.9 (c)(9)
	Product Code:	CEK
	Common/Classification Name:	Biuret (Colorimetric), Total Protein
	Trade/Device Name:	ACE Calcium-Arsenazo Reagent
	Regulation Number:	21 C.F.R. § 862.1145
	Regulation Name:	Calcium Test System
	Regulatory Class:	Class 2
	Product Code:	CJY
	Common/Classification Name:	Azo Dye, Calcium

	Trade/Device Name:	ACE Inorganic Phosphorus U.V. Reagent
	Regulation Number:	21 C.F.R. § 862.1580
	Regulation Name:	Phosphorus (Inorganic) Test System
	Regulatory Class:	Class 1, Reserved
	Product Code:	CEO
	Common/Classification Name:	Phosphomolybdate (Colorimetric), Inorganic Phosphorus
Predicate Devices:	Manufacturer for analyzer/reagent system predicate: Alfa Wassermann ACE plus ISE/Clinical Chemistry System ACE Reagents (K931786)	
Device Descriptions:	In the ACE Albumin Reagent assay, Bromcresol green binds specifically to albumin to form a green colored complex, which is measured bichromatically at 629 nm/692 nm. The intensity of color produced is directly proportional to the albumin concentration in the sample. In the ACE Total Protein Reagent assay, cupric ions react with the peptide bonds of proteins under alkaline conditions to form a violet colored complex which is measured bichromatically at 544 nm/692 nm. The intensity of color produced is directly proportional to the total protein concentration in the sample. In the ACE Calcium-Arsenazo Reagent assay, calcium reacts with Arsenazo III in an acidic solution to form a blue-purple colored complex, which is measured bichromatically at 647 nm/692 nm. The intensity of color produced is directly proportional to the calcium concentration in the sample. In the ACE Inorganic Phosphorus U.V. Reagent assay, under acidic conditions, inorganic phosphorus in serum reacts with ammonium molybdate to form an unreduced phosphomolybdate complex, which absorbs strongly at 340 nm. The increase in absorbance, measured bichromatically at 340 nm/378 nm, is directly proportional to the amount of phosphorus in the sample.	
Intended Use:	Indications for Use: The ACE Albumin Reagent is intended for the quantitative determination of albumin concentration in serum using the ACE Axcel Clinical Chemistry System. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.	

	The ACE Total Protein Reagent is intended for the quantitative determination of total protein concentration in serum using the ACE Axcel Clinical Chemistry System. Total protein measurements are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Calcium-Arsenazo Reagent is intended for the quantitative determination of calcium concentration in serum using the ACE Axcel Clinical Chemistry System. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms). This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. The ACE Inorganic Phosphorus U.V. Reagent is intended for the quantitative determination of inorganic phosphorus concentration in serum using the ACE Axcel Clinical Chemistry System. Measurements of inorganic phosphorus are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases and vitamin D imbalance. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Technological Characteristics:	The ACE Albumin Reagent consists of a single reagent bottle. The reagent contains Bromcresol green and acetate buffer. The ACE Total Protein Reagent consists of a single reagent bottle. The reagent contains copper sulfate, sodium potassium tartrate, potassium iodide and sodium hydroxide. The ACE Calcium-Arsenazo Reagent consists of a single reagent bottle. The Reagent contains Arsenazo III. The ACE Inorganic Phosphorus U.V. Reagent consists of a single reagent bottle. The reagent contains ammonium molybdate and sulfuric acid.
Performance Data:	Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Axcel Clinical Chemistry System included precision, accuracy, and detection limit data. ACE Albumin Reagent Precision: In testing conducted at four albumin levels for 22 days, the within-run CV ranged from 0.9 to 1.7%, and total CV ranged from 1.2 to 2.0%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.0 to 1.6% and total CV ranged from 0.0 to 2.3%. Accuracy: In the correlation study, 118 samples with albumin values ranging from 0.4 to 6.4 g/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9959, a standard error estimate of 0.08, a confidence interval slope of 0.980 to 1.013, and a confidence interval intercept of -0.04 to 0.10. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9894 to 0.9966, standard error estimates of 0.08 to 0.13, confidence interval slopes of 0.946 to 1.037, and a confidence interval intercepts of -0.14 to 0.39. Detection limit: The detection limit was 0.09 g/dL. ACE Total Protein Reagent Precision: In testing conducted at four total protein levels for 22 days, the within-run CV ranged from 0.8 to 2.4%, and total CV ranged from 1.0 to 2.9%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.7 to 1.3% and total CV ranged from 0.8 to 1.6%.

	Accuracy: In the correlation study, 121 samples with total protein values ranging from 0.4 to 13.5 g/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9977, a standard error estimate of 0.12, a confidence interval slope of 0.978 to 1.002, and a confidence interval intercept of -0.12 to 0.06. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9932 to 0.9987, standard error estimates of 0.09 to 0.24, confidence interval slopes of 0.973 to 1.047, and a confidence interval intercepts of -0.41 to 0.19. Detection limit: The detection limit was 0.15 g/dL. ACE Calcium-Arsenazo Reagent Precision: In testing conducted at four calcium levels for 22 days, the within-run CV ranged from 1.3 to 2.3%, and total CV ranged from 1.4 to 2.3%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.8 to 1.4% and total CV ranged from 1.1 to 2.9%. Accuracy: In the correlation study, 111 samples with calcium values ranging from 0.7 to 14.5 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9935, a standard error estimate of 0.22, a confidence interval slope of 0.998 to 1.042, and a confidence interval intercept of -0.50 to -0.08. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9895 to 0.9977, standard error estimates of 0.16 to 0.23, confidence interval slopes of 0.969 to 1.075, and a confidence interval intercepts of -0.43 to 0.42. Detection limit: The detection limit was 0.11 mg/dL. ACE Inorganic Phosphorus U.V. Reagent Precision: In testing conducted at four phosphorus levels for 22 days, the within-run CV ranged from 1.4 to 1.9%, and total CV ranged from 1.5 to 2.5%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.6 to 3.2% and total CV ranged from 1.0 to 3.9%.

	Accuracy: In the correlation study, 110 samples with phosphorus values ranging from 0.6 to 19.6 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9983, a standard error estimate of 0.16, a confidence interval slope of 0.994 to 1.017, and a confidence interval intercept of -0.06 to 0.05. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9977 to 0.9996, standard error estimates of 0.11 to 0.19, confidence interval slopes of 1.014 to 1.067, and a confidence interval intercepts of -0.33 to 0.09. Detection limit: The detection limit was 0.07 mg/dL.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Vice President, Quality and Regulatory Affairs
4 Henderson Drive
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Re: k113374
Trade/Device Name: ACE Albumin Reagent, ACE Total Protein Reagent, ACE Calcium-Arsenazo Reagent, ACE Inorganic Phosphorus U.V. Reagent
Regulation Number: 21 CFR§ 862.1035
Regulation Name: Albumin test system
Regulatory Class: Class II
Product Code: CIX, CEK, CJY, CEO
Dated: May 29, 2012
Received: May 31, 2012

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 113374

Device Name: ACE Albumin Reagent

Indications for Use: The ACE Albumin Reagent is intended for the quantitative determination of albumin concentration in serum using the ACE Axcel Clinical Chemistry System. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Total Protein Reagent

Indications for Use: The ACE Total Protein Reagent is intended for the quantitative determination of total protein concentration in serum using the ACE Axcel Clinical Chemistry System. Total protein measurements are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In vitro* Diagnostic Devices (OIVD)

Division Sign-Off
Office of *In vitro* Diagnostic Device
Evaluation and Safety

510(k) 113374

Indications for Use

510(k) Number (if known): K113374

Device Name: ACE Calcium-Arsenazo Reagent

Indications for Use: The ACE Calcium-Arsenazo Reagent is intended for the quantitative determination of calcium concentration in serum using the ACE Axcel Clinical Chemistry System. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms). This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Inorganic Phosphorus U.V. Reagent

Indications for Use: The ACE Inorganic Phosphorus U.V. Reagent is intended for the quantitative determination of inorganic phosphorus concentration in serum using the ACE Axcel Clinical Chemistry System. Measurements of inorganic phosphorus are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases and vitamin D imbalance. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of *In vitro* Diagnostic Devices (OIVD)

Division Sign-Off
Office of *In vitro* Diagnostic Device
Evaluation and Safety

510(k) 113374